



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,000	09/16/2003	Kalim Mir	8654/2182	3911
29933	7590	07/12/2006		EXAMINER
PALMER & DODGE, LLP				LU, FRANK WEI MIN
KATHLEEN M. WILLIAMS				
111 HUNTINGTON AVENUE			ART UNIT	PAPER NUMBER
BOSTON, MA 02199			1634	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,000	MIR, KALIM	
	Examiner	Art Unit	
	Frank W. Lu	1634	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 September 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-136 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-136 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Substitute Specification

1. Although applicants indicated that they submitted a substitute specification with marked-up version (see transmittal letter filed on July 19, 2004), the examiner could not locate a substitute specification with marked-up version. According to 37 CFR 1.125 (c), the substitute specification filed on April 19, 2004 has not been entered. In order to speed prosecution, the restriction below is based on the claims in the substitute specification and applicant is required to submit a substitute specification with marked-up version in response to this office action.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-26, 124, 125, and 136, drawn to a method for producing a molecular array, classified in class 435, subclass 287.2.
 - II. Claims 27, 105, 117-121, 124, 125, and 136, drawn to a molecular assay (claims 27, 105, 124, 125, and 136) and a biosensor comprising a molecular assay (claims 117- 121, 124, 125, and 136), classified in class 536, subclass 23.1.
 - III. Claims 28-54, 96, 97, 124, 125, and 136, drawn to use of a molecular array in a method of identifying one or more target molecules in a sample, classified in class 435, subclass 6.
 - IV. Claims 55-59, 76-81, 96, 97, 124, 125, and 136, drawn to a method for typing single nucleotide polymorphisms (SNPs) and mutations in nucleic acids, classified in class 435, subclass 6.

- V. Claims 60-66, 96, 97, 124, 125, and 136, drawn to a method for determining the complete or partial sequence of a target nucleic acid, classified in class 435, subclass 6.
- VI. Claims 67-70, 96, 97, 124, 125, and 136, drawn to a method for determining the number of sequence repeats in a sample of nucleic acid, classified in class 435, subclass 6.
- VII. Claims 71-75, 96, 97, 124, 125, and 136, drawn to a method for analyzing the expression of one or more genes in a sample, classified in class 435, subclass 6.
- VIII. Claims 82-86, 96, 97, 124, 125, and 136, drawn to a method for obtaining allele frequencies by single molecule counting of pooled DNA, classified in class 435, subclass 6.
- IX. Claims 87-97, 124, 125, and 136, drawn to a method for determining the complete or partial sequence of a target nucleic acid, classified in class 435, subclass 6.
- X. Claims 98-101, drawn to a method for determining the complete or partial sequence of a target nucleic acid, classified in class 435, subclass 6.
- XI. Claims 102-104, 124, 125, and 136, drawn to a method for arraying a plurality of nucleic acid molecules, classified in class 435, subclass 287.2.
- XII. Claims 106-116, 122-125, and 136, drawn to a method for identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample, classified in class 435, subclass 6.
- XIII. Claims 126-136, drawn to a method for determining haplotypes by probing single molecules immobilized on a solid phase in a spatially addressable manner (claims

126 and 127) and a method for haplotyping (claims 128-136), classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and III to XIII and Group II are distinct and independent inventions in that they are directed to different methods and a product. As a result, different and distinct searches will have to be performed. For example, the search required for Groups I and III to XIII such as the method steps in the independent claims of Groups I and III to XIII is not required for Group II.

Group I and Groups III to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as producing a molecular array in claim 1 is not required for Groups III to XIII while the search required for Group III such as identifying one or more target molecules in a sample in claim 28, the search required for Group IV such as typing single nucleotide polymorphisms (SNPs) and mutations in nucleic acids in claim 55, the search required for Groups V, IX, and X such as determining the complete or partial sequence of a target nucleic acid in claims 60, 87, and 98, the search required for Group VI such as determining the number of sequence repeats in a sample of nucleic acid in claim 67, the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a

sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group I.

Group III and Groups IV to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as identifying one or more target molecules in a sample in claim 28 is not required for Groups IV to XIII while the search required for Group IV such as typing single nucleotide polymorphisms (SNPs) and mutations in nucleic acids in claim 55, the search required for Groups V, IX, and X such as determining the complete or partial sequence of a target nucleic acid in claims 60, 87, and 98, the search required for Group VI such as determining the number of sequence repeats in a sample of nucleic acid in claim 67, the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group III.

Group IV and Groups V to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as typing single nucleotide polymorphisms (SNPs) and mutations in nucleic acids in claim 55 is not required for Groups V to XIII while the search required for Groups V, IX, and X such as

determining the complete or partial sequence of a target nucleic acid in claims 60, 87, and 98, the search required for Group VI such as determining the number of sequence repeats in a sample of nucleic acid in claim 67, the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group IV.

Groups V, IX, and X and Groups VI to VIII, and XI to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Groups V, IX, and X such as determining the complete or partial sequence of a target nucleic acid in claims 60, 87, and 98 is not required for Groups VII, VIII, and XI to XIII while the search required for Group VI such as determining the number of sequence repeats in a sample of nucleic acid in claim 67, the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Groups V, IX, and X.

Group V and Groups IX and X are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as step e) of claim 60 is not required for Groups IX and X while the search required for Groups IX and X such as step (ii) of claims 87 and 98 is not required for Group V.

Group VI and Groups VII to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as determining the number of sequence repeats in a sample of nucleic acid in claim 67 is not required for Groups VII to XIII while the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Groups IX and X such as determining the complete or partial sequence of a target nucleic acid in claims 87 and 98, the search required for Group XI such as arraying a plurality of nucleic acid molecules in claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group VI.

Group VII and Groups VIII to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VII such as analyzing the expression of one or more genes in a sample in claim 71 is not required for Groups

VIII to XIII while the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82, the search required for Groups IX and X such as determining the complete or partial sequence of a target nucleic acid in claims 87 and 98, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group VII.

Group VIII and Groups IX to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VIII such as obtaining allele frequencies by single molecule counting of pooled DNA in claim 82 is not required for Groups IX to XIII while the search required for Groups IX and X such as determining the complete or partial sequence of a target nucleic acid in claims 87 and 98, the search required for Group XI such as step (iii) of claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group VIII.

Groups IX and X and Groups XI to XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Groups IX and X such as determining the complete or partial sequence of a target nucleic acid in claims 87 and 98 is not required for Groups XI to XIII while the search required for Group XI such as arraying

Art Unit: 1634

a plurality of nucleic acid molecules in claim 102, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group IX and X.

Groups IX and X are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IX such as step (iv) in claim 87 is not required for Group X and the search required for Group X such as step (iv) in claim 98 is not required for Group IX.

Group XI and Groups XII and XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group XI such as arraying a plurality of nucleic acid molecules in claim 102 is not required for Groups XII and XIII while the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim 106, and the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group XI.

Groups XII and XIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group XII such as identifying and/or characterizing one or more molecules of a plurality of molecules present in a sample in claim

Art Unit: 1634

106 is not required for Group XIII while the search required for Group XIII such as determining haplotypes in claim 126 is not required for Group XII

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on two applications (GB0106635.6 and GB01118876.6) filed in United Kingdom on March 16, 2001 and August 2, 2001. It is noted, however, that applicant has not filed a certified copy of these application as required by 35 U.S.C. 119(b).

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

July 7, 2006

Frank Lu
FRANK LU
PRIMARY EXAMINER